Catalytica
Pharmaceuticals

1246 '99 NOV 16 A11:30

November 15, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Draft Guidance for Industry on ANDA's: Blend Uniformity Analysis; Availability [Docket No. 99D-2635]

Dear Sir/Madam:

Reference is made to the Draft Guidance for Industry on ANDA's: Blend Uniformity Analysis; Availability [Docket No. 99D-2635]. Catalytica Pharmaceuticals, Inc. would like to provide the following comments regarding this guidance to the agency:

- BUA testing is a useful component of the validation process to ensure adequacy of mixing. However, BUA testing is not appropriate as a routine in-process test. Once a process is validated, content uniformity testing is adequate to demonstrate final dosage form uniformity and meet cGMP requirements. The draft guidance is essentially requiring the validation process be repeated for every batch.
- Routine BUA testing will not add to the quality or safety of pharmaceuticals, but will significantly increase the cost to manufacture and test pharmaceutical products. Increased production costs are likely to result in increased costs to the consumer.
- BUA testing, as a routine in-process test, is not required for new drug approval. Therefore, this test should not be required for generic products.

Thank you for your attention to these comments. If you have any questions regarding these comments, please contact me at 252-707-7913.

Sincerely,

Beverly M. Lewis

Beverly Lewis, RAC
Manager, Regulatory Affairs
Pharmaceutical Research and Development

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